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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
US7957,045	10/24/97	VALDGE	S FB1517US3

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EXAMINER

BERCH, M

ART UNIT  
1611

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks****Best Available Copy**

<b>Office Action Summary</b>	Application No. <b>08/957,045</b>	Applicant(s) <b>Daluge</b>
	Examiner <b>Mark L. Berch</b>	Group Art Unit <b>1611</b>

Responsive to communication(s) filed on Nov 17, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 9 and 18-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 9 and 18-20 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. There still remains previous point 1. Applicants' traverse on this point is unconvincing. The references that applicants refer to are not of record. Further, the definitions provided are irrelevant to the current circumstance. The first refers to monosaccharide and the second refers to a pentose, but neither are present here.
2. "Such as" is improper alternative language (In re Kingston, 65 USPQ 371).
3. Phosphonyl is indefinite. It means the radical derived from the removal of OH from a phosphonic acid, but which one?
4. The heterocycle definition is indefinite for reasons set forth in point 5. What is the number and nature of the heteroatoms present?
5. The word "atom" appears twice in the 4th from last line of page 3.

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6. As stated previously in point 4, the first R<sup>3</sup> choice is completely covered by the second choice. That is, the carbocyclics are already completely embraced by the hydrocarbyl. Thus, the function of this material is unknown.

7. The point 4 ambiguity with "group" remains. Its is still unclear whether that covers benzyl; it is unclear whether the entire group has to be carbocyclic, or whether the mere presence of a carbocycle is enough.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over  
1224  
Daluge '697 in view of Vince or Daluge '671, further in view of newly cited Norbeck,  
1607  
Vince, Bothwick or Shealy.

The reasons were given previously; the traverse on this point is unpersuasive. The sole difference is that while the prior art does the reaction with the amine protected (with R<sup>3</sup>), the claimed process is done with the amine not protected. Applicants call this difference "significant", but this variation is shown in the secondary art. Applicants urge improvements, such as avoiding "low yields", but applicants must establish differences by direct, side by side comparisons and demonstrate that these differences are unexpected.

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Also, applicants refer to the removal of the protecting group as being "not trivial". It should be noticed however, that applicants also have to remove the protecting group; they simply do it at an earlier stage of the synthesis, when going from (I) to (II). Thus, this argument would require showing that removal at the earlier stage unexpectedly gave fewer problems on deprotection than removal at a later stage.

The claims have been amended to require the use of aqueous acid for the orthoformate condensation. The new cited references show this directly. In Norbeck, see Column 11, 13-14. This is exemplified at Column 19, step G, which uses aqueous Hydrochloric acid, just as applicants do. In Vince see Figure 1, cyclization of 3a. Ex 11 uses the same procedure. In Bothwick, see paragraph bridging columns 17-18, using the same procedure. In Shealy, see Example 1, which uses the same acid. These references thus show that the use of aqueous acid is conventional for orthoformate cyclizations.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 413,544 in view of newly cited Norbeck, Vince, Bothwick or Shealy.

The primary reference was discussed previously. The use of orthoformate is disclosed at page 4, line 43. The reference is silent on the use of aqueous acid; the secondary references, as indicated above, show that this is conventional or orthoformate cyclizations. Applicants argued that the process "exclude amines where R<sup>3</sup> is OR or OH." This is simply not so. Indeed, OH and protected OH are recited in

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Claim 9 and page 10 calls them "preferred groups". The group in the reference is a protected OH.

Claims 9, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Norbeck, Vince, Bothwick or Shealy, in view of EP 413,544 or Daluge '697.

The primary references are discussed above. These differ only in that they use in the 5-position the unsubstituted amino, whereas applicants use the formyl amino. However, the secondary references teach that both are alternatively useable for this cyclization. Note that Q in EP 413,544 and NHR<sup>2</sup> in Daluge '697 are both defined as being either amino or formyl amino.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-

4718.



Mark L. Berch

Primary Examiner

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January 22, 1999